UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Kimberly Bullock and Clark Bullock,

Plaintiffs

v.

General Electric Company, GE Healthcare, Inc., and GE Healthcare AS,

Defendants

Case No. 1:08 GD

MDL No. 1909

Judge Dan Aaron Polster

IN RE: GADOLINIUM BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION

COMPLAINT

A. Jurisdiction

Plaintiff

1. The plaintiffs are residents and citizens of the state of Ohio.

GE Defendants

2. Defendant General Electric Company is a New York corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431. Defendant General Electric Company is a resident and citizen of both New York and Connecticut. Defendant General Electric Company is the parent company of Defendant GE Healthcare, Inc. and Defendant GE Healthcare AS.

3. At all times relevant, Defendant General Electric Company was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into

interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Omniscan.™

4. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant GE Healthcare, Inc. is a subsidiary of General Electric Company.

5. At all times relevant, Defendant GE Healthcare, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Omniscan™

6. Defendant GE Healthcare AS is a Norweigan coporation with it's principal place of business in the kingdom of Norway.

7. At all times relevant, Defendant GE Healthcare AS. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Omniscan™

Amount in controversy

8. The amount in controversy exceeds $75,000.00, exclusive of interest and costs.

Doing business in Ohio

9. The defendants do, and at all times mentioned in this complaint did business in Ohio, through the sale of the contrast solution identified above to Riverside Hospital and other institutions in the state.

10. The defendants do, and at all times mentioned in this complaint did business in Ohio, through

the sale of products other than contrast solutions to customers in the state.

Tortious injury in Ohio

11. This complaint alleges that the defendants caused tortious injury to the plaintiff Mrs. Bullock in Ohio as a result of complications from the administration of defendants' gadolinium-containing contrast solution in the state.

B. Direct Filing of Case into MDL No. 1909

12. This complaint is being filed in the MDL pursuant to Case Management Order #3. Otherwise the proper jurisdiction and venue to file this case in would be the Southern District of Ohio.

C. Nephrogenic Systemic Fibrosis

13. Nephrogenic Systemic Fibrosis, also known as Nephrogenic Fibrosing Dermopathy and referred to hereinafter as NSF, is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin.

14. NSF is caused by gadolinium used in contrast solutions used in enhanced MRI and MRA. In those who will develop NSF, symptoms can begin days-to-months after injection of contrast solution containing gadolinium. Published literature puts the reported time period for symptoms to appear from as short as two days to as long as 18 months.

15. Fibrotic and edematous changes caused by NSF produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF can progress to the point where a person effectively loses use of arms, legs, hands, and/or feet.

16. NSF skin changes frequently begin as darkened patches or plaques and progress to a woody texture and are accompanied by burning, itching, and/or severe pain in the areas of involvement.

17. NSF can cause fibrosis and scarring of lungs, heart, liver, and muscles and can be fatal. It

is a progressive disease with no known cure and no consistently effective treatment.

18. The symptoms of NSF were observed and discussed in scientific literature years before the condition was given a name or the cause was understood. The NSF and/or NFD terminology has been used for about ten years. Before that, the condition was referred to as scleromyxedema, scleroderma, or some other connective tissue disease.

19. NSF has been reported thus far only in people whose kidney function was compromised at the time of injection with gadolinium-containing contrast solution.

20. NSF did not exist until gadolinium-containing contrast solutions came into use for enhancing MRI and MRA scans.

D. Harm to the plaintiff

21. Plaintiff Kimberly Bullock underwent an MRI using the Defendant's gadolinium-containing contrast agent on August 6, 2006 at Riverside Methodist Hospital in Columbus, OH.

22. Mrs. Bullock was diagnosed with end stage renal disease in March of 2004. She began receiving dialysis treatments and continued until she received a renal transplant on May 2, 2007.

23. As a result of Plaintiff's renal insufficiency and exposure to gadolinium agents, Plaintiff was diagnosed with Nephrogenic Systemic Fibrosis, confirmed via biopsy slides. Due to her NSF, Plaintiff:

a. developed intractable excrutiating and unrelenting pain that requires daily use of several medications to control it;

b. is so weak and debilitated that she can no longer hold onto things or mover her joints and con only ambulate with use of a wheelchair, or a

walker;

c. has lost much of the feeling in her extremeties and joints, further increaing her difficulty walking;

d. has such severe tightening and stiffening of her skin and muscles that she has an impared ability to bend and move;

e. developed progressively and continually worsening hardness and stiffness in her hands and arms, impairing her ability to perform her own personal daily activities of living;

f. suffers such incessant and intense itching all over her body;

g. is unable to walk without the use of a walker or wheelchair, and can no longer drive;

h. has permanently discolored and disfigured skin and permanently impaired joints;

i. is in jeapordy of having her heart and lungs impaired;

j. has been left with permanently disfigured skin and an uncertain prognosis with an incurable, progressibely disabling systematic disease for which no effective therapy presently exists;

k. has had various suggested treatments for NSF tried by her doctors with little success; and

l. has incurred, is incurring and will incur in the future, extensive medical expenses for treatment of NSF.

24. In June 2006, the U.S. Food and Drug Administration (FDA) issued Public Health

Advisory Alerts concerning the development of serious, sometimes fatal, NSF/NFD after exposure to gadolinium based contrast agents.

25. Defendants knew or should have known about the significant health risks of administering gadolinium-containing contrast agents to patients with renal insufficiency long before Plaintiff Kimberly Bullock was injected with the contrast dye and long before the FDA issued the alert described in the preceding paragraph. These risks included, but were not limited to, the risk of developing NFS/NFD. Nevertheless, Defendants failed to either design their product in a way that would account for the fact that patients like Plaintiff, with impaired kidney function would receive it and thereby be exposed to free gadolinium or, at the very least, warn Plaintiff, her physicians and the medical and scientific community of the risk.

26. Despite the availability of numerous reports, studies, assessments and other clinical data linking NSF/NFD to use of gadolinium-containing contrast agents in patients with renal insufficiency, Defendants have consistently failed to revise their design of their gadolinium-containing contrast agents or to warn consumers and/or health care providers of such risks.

27. Further, despite the availability of numerous reports, studies, assessments and other clinical data linking NSF/NFD to use of gadolinium-containing contrast agents in patients with renal insufficiency, Defendants failed to revise package inserts, Material Safety Data Sheets and other product related literature to reflect this potential danger of gadolinium-induced NSF/NSD or to conduct appropriate post-marketing communications in order to convey adequate warnings.

28. During the times relevant to this case, Defendants, failed to take prompt, reasonable, and effective measures to alert the appropriate members of the health care community and its

patients, including, but not limited to, renal patients, nephrologists and other physicians, radiologists, administrators, technicians and hospital/radiology supply personnel, to the serious adverse health risks presented by their gadolinium-containing contrast agents.

29. Had Plaintiff and/or her health care providers known of the serious health risks associated with the use of gadolinium-containing contrast agents on patients with renal insufficiencies, they would not have used the gadolinium based agent during her MRI procedures and therefore he would not have been afflicted with NSF/NFD.

30. As a result of her diagnosis, Plaintiff Kimberly Bullock suffered from conscious pain and suffering due to a painful, debilitating condition and significant emotional and mental anguish.

E. Plaintiff Clark Bullock's loss of consortium claim

31. The plaintiffs are, and at the times mentioned in this complaint were, husband and wife.

32. Plaintiff Clark Bullock has lost, and will lose in the future, a substantial measure of his wife's consortium as a result of NSF with which she suffers.

F. First basis for imposing liability for compensatory damages:

Strict Liability in Tort

33. The defendants developed, patented, manufactured, distributed, and marketed the contrast solution Omniscan.

34. The contrast solution was not materially altered between the time it was placed into the stream of commerce by the defendants and the time it was administered to the plaintiff.

35. The contrast solution was unreasonably dangerous, not reasonably safe, and/or did not meet reasonable consumer expectations, because of:

a. design defects,

b. use defects (inadequate warnings), and/or

c. defects attributable to inadequate testing.

G. Second basis for imposing liability for compensatory damages:

Negligence

36. The defendants negligently designed and tested the contrast solution, and they negligently failed to warn of the risk of the contrast solution when given to people with impaired kidney function.

H. Third basis for imposing liability for compensatory damages:

Breach of Implied Warranty

37. A warranty that a product is reasonably fit for its intended purpose is imposed by law on the seller of the product, including the defendants as sellers of the contrast solution.

38. The plaintiff reasonably relied on the belief that the contrast solution would be reasonably fit for its intended purpose.

39. The defendants breached this implied warranty, because the contrast solution was not reasonably fit for its intended purpose.

I. Fourth basis for imposing liability for compensatory damages:

Breach of Express Warranty

40. The defendants expressly warranted that the contrast solution would be reasonably fit for its intended purpose.

41. The plaintiff reasonably relied on the belief that the contrast solution would be reasonably fit for its intended purpose.

42. The defendants breached this express warranty, because the contrast was not reasonably fit for its intended purpose.

J. Basis for allowing punitive damages:

Deliberate, Intentional, Reckless and/or Malicious Conduct

43. The totality of the defendants' conduct, as described in this complaint, is susceptible of being interpreted by reasonable people as demonstrating an irresponsible attitude toward the safety and health of those who would receive its contrast solution, including the plaintiff, which was deliberate, willful, intentional, reckless, and/or malicious.

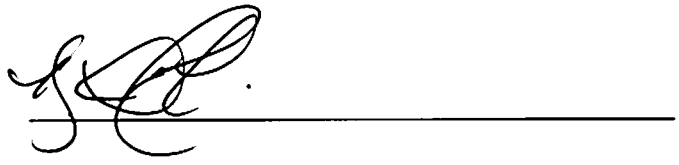
K. Relief requested

Accordingly, the plaintiff asks for judgments against the defendants for:

a. economic and noneconomic compensatory damages, and

b. punitive damages.

A jury trial is requested



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